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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,848	02/01/2002	Dirk Kostrewa	13232 US2 (C38435/128425)	5651

7590

05/06/2003

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EXAMINER
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SAIDHA, TEKCHAND

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/06/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

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**DETAILED ACTION**

*Written*

***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-11, drawn to a process of designing and producing a modified phytase, classified in class 435, subclass 471.
  - II. Claims 12-15 and 24, drawn to a modified *Aspergillus* phytase, classified in class 435, subclass 196.
  - III. Claims 16-23, drawn to DNA encoding a modified phytase and transformed host cells classified in class 435, subclass 325.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a different process such as a phytase produced by a mutagenized *Aspergillus*.
3. Inventions of Group I and Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as

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claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a different process such as by random mutagenesis.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Mr. Kevin Hooper on 5/18/99 a provisional election was made with traverse to prosecute the invention of Group II, claims 12-15 and 24.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-11 and 16-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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***Priority***

8. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Specification***

9. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s): sequences are disclosed in the instant application which are not identified by a sequence identifier (SEQ ID NO:). Additionally, no Sequence Listing and computer readable form (floppy disk) of the sequences is provided.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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12. Claim 12 is indefinite as phytases are known to contain peptide leader sequences which are cleaved to obtain the mature polypeptide. It is not clear if the modified phytases are those with or without a peptide leader sequence.

13. Claim 12 is unclear as to what is meant by "corresponding". Since phytases would have different lengths and amino acid sequences, it is not clear what amino acid of a phytase would be considered to "correspond" to the position 27 amino acid of *A. niger*.

14. Claims 13, 14 and 24 are indefinite because they depend upon an indefinite base claim and fail to correct the problem.

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 12 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a modified *Aspergillus fumigatus* phytase with the specified mutations of amino acid position 27, does not reasonably provide enablement for any *Aspergillus* phytase with the specified mutations at amino acid position 27. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of

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direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, and (6) the breadth of the claims. As each *Aspergillus* phytase has a different amino acid sequence and different number of amino acids, the specified changes in the amino acid sequence at position 27 of the *A.fumigatus* phytase would not necessarily correspond to amino acid 27 of another phytase other than *A. fumigatus*. With different amino acid sequences among phytases, a change of the position 27 amino acid to Ala, Val, Leu, Ile, Thr, or Asn would not be expected to provide an improvement in specific activity. The breadth of the claim encompasses any phytase with the specified amino acid substitutions at position 27. A large amount of experimentation would be required to determine which phytase could be modified at position 27 to obtain an improved phytase. As guidance for making a modified phytase are provided only for *A. fumigatus* and the example provided of a modified phytase is an *A. fumigatus* phytase, a person of skill in the art would only know how to make and use a modified *A. fumigatus* phytase.

17. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a modified *Aspergillus fumigatus* phytase comprising the specified mutations, does not reasonably provide enablement for any *Aspergillus* phytase with the specified mutations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a

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disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, and (6) the breadth of the claims. The breadth of the claim encompasses any phytase with the specified amino acid substitutions. As each phytase has a different amino acid sequence and different number of amino acids, the specified changes in the amino acid sequence would not work in any other phytase except that from *A. fumigatus*. With different amino acid sequences among phytases, the specified mutations would not produce an improvement in specific activity of any other phytase. A large amount of experimentation would be required to determine the source of an unmodified phytase which could be modified to obtain an improved phytase. As guidance for making a modified phytase are provided only for *A. fumigatus* and the examples provided of modified phytases are *A. fumigatus* phytase, a person of skill in the art would only know how to make and use a modified *A. fumigatus* phytase.

***Allowable Subject Matter***

18. Claims 12-15 and 24 are allowable over the prior art of record. While teach the *Aspergillus fumigatus* phytase, the prior art does not teach or suggest a modified phytase with the specified amino acid substitutions.

19. No claims are allowed.

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20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

**Peter Tung**

2nd office action

***Claim Rejections - 35 USC § 112***

21. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

22. Claims 15 and 33-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.



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23. Claims 15 and 33-44 are unclear as to the sequence comprising the amino acid modifications specified. For example, claim 15 has a modification of Q27L to *A. fumigatus* phytase. However, Q27 is in reference to the glutamine of *A. fumigatus* which corresponds to position 27 of *A. niger*. Claim 33 specifies that SEQ ID NO: 3 comprises a modification of Q27L. However, SEQ ID NO: 3 does not contain a glutamine at position 27 but instead has a glutamine at position 23.